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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,915	06/27/2003	Stephen L. Hoffman	ABIOS.023A	7068

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EXAMINER	
WHALEY, PABLO S	

ART UNIT	PAPER NUMBER
1631	

NOTIFICATION DATE	DELIVERY MODE
08/21/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/608,915	HOFFMAN ET AL.	
	Examiner	Art Unit	
	PABLO WHALEY	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *85-92 and 107-118* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *85-92 and 107-118* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims Under Examination

Claims 85-92 and 107-118 are pending. Claims 1-84 and 93-106 have been cancelled.

Priority

This application has been granted the benefit of priority to US Provisional Application 60/392,843, filed June 28, 2002.

Withdrawn Rejections

The rejection of claims 85-92, 107-109, 111, and 118 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicant's amendments filed 04/08/2008.

The rejection of claims 85-92 and 109-118 under 35 U.S.C. 103(a) as being obvious over Rognan et al. in view of Welch et al. is withdrawn in view of applicant's arguments, filed 04/08/2008, that neither reference teaches scaling and combining binding affinities with values between 0 and 1.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 85-92, 107-113, and 115-118 are rejected under 35 U.S.C. 101 because these claims are drawn to non-statutory subject matter. These claims are rejected for the following reasons.

The instant claims are drawn to methods of assessing the binding affinity between a candidate peptide and target sequence. For a process to be statutory, it must provide: (1) a practical application by physical transformation (i.e. reduction of an article to a different state or thing), or (2) a practical application that produces a concrete, tangible, and useful result [State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998)], [AT&T Corp. v. Excel Communications Inc. (CAFC 50 USPQ2d 1447 (1999)]. As noted in State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998), the statutory category of the claimed subject matter is not relevant to a determination of whether the claimed subject matter produces a useful, concrete, and tangible result. The question of whether a claim encompasses statutory subject matter should not focus on which of the four categories of subject matter a claim is directed to a process, machine, manufacture, or composition of matter--but rather on the essential characteristics of the subject matter, in particular, its practical utility.

In the instant case, the claimed processes do not result in a physical transformation of matter. Where a claimed method does not result in a physical transformation of matter, it may be statutory where it recites a result that is concrete (i.e. reproducible), tangible (i.e. communicated to a user), and useful result (i.e. a specific and substantial). In particular, claims 85, 90, 107, 111, 112, and 118 result in outputting combined binding affinities "to a user or a memory." However, while outputting data to a user provides a tangible result, outputting data to a memory is not a tangible result because it does not communicate a result to a user in a user readable format. Therefore the claimed methods do not recite a practical application of a 35 U.S.C. 101 Judicial exception and is not statutory. This rejection could be overcome by amendment of the claims to be limited to outputting data to a user.

By similar reasoning, the method of claim 109 also lacks a tangible result. The claimed process recites a step for outputting combined binding affinities "to a user or a memory", but results in "evaluating" binding affinities. However, evaluating data is not a tangible result because it is does not communicate a result in a form that is useful to the user of the process (i.e. a user readable format). Therefore the claimed system does not recite a practical application of a 35 U.S.C. 101 Judicial exception and is not statutory. This rejection could be overcome by amendment of the claims to be limited to outputting data to a user in a user readable format, outputted to a display.

Response to Arguments

Applicant's arguments, filed 4/08/2008, that the claims are statutory view of the claim amendments have been fully considered but are not persuasive. In response, claims 85, 90, 107, 111, 112, and 118 result in outputting combined binding affinities "to a user or a memory." However, while outputting data to a user provides a tangible result, outputting data to a memory is not a tangible result because it does not communicate a result to a user in a user readable format. Therefore the claimed methods do not recite a practical application of a 35 U.S.C. 101 Judicial exception and is not statutory. This rejection could be overcome by amendment of the claims to be limited to outputting data to a user.

By similar reasoning, the method of claim 109 also lacks a tangible result. The claimed process recites a step for outputting combined binding affinities "to a user or a memory", but results in "evaluating" binding affinities. However, evaluating data is not a tangible result because it is does not communicate a result in a form that is useful to the user of the process (i.e. a user readable format). Therefore the claimed system does not recite a practical application of a 35 U.S.C. 101 Judicial exception and is not statutory. This rejection could be overcome by amendment of the claims to be limited to outputting data to a user in a user readable format, outputted to a display.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 85-92 and 109-118 are rejected under 35 U.S.C. 103(a) as being obvious by Daniel et al. (Journal of Immunology, 1998, Vol. 162, No. 2, p.617-624), in view of Wang et al. (Journal of Molecular Modeling, 1998, Vol. 4, p.379-394).

Daniel teaches two different methods for predicting binding affinities between MHC class I proteins and epitopes [Abstract, p.618, Col. 2, ¶4 and ¶5, and p.620], a matrix-based method and a non-linear method. Daniel provides predicted binding affinity scores representing likelihood of binding [Tables I and II]. Daniel teaches the scaling of binding affinity data from 0 to 10 [p.619, Col. 2, ¶5 and p.620, Col. 2, ¶1]. The scale combines predictive performance scores for low affinity peptides (scores 0-4) together with high affinity pepetides (scores 5-10) [p.620, Col. 2, ¶2].. Daniel teaches comparing two different predictive strategies by adjusting their affinity scores to the scale of 0 to 10 [p.620, Col. 2, ¶2], and outputting scaled binding affinity scores [Fig. 3 and Fig. 4]. Daniel teaches candidate peptide data divided into 9-mer fragments [p.620, Col. 1]. Daniel teaches binding affinity scores represented as normalized IC-50 values representing peptide binding Ka values [Fig. 3 and p.620, Col. 2, ¶1].

Daniel does not teach scaling binding affinities from 0 to 1, as in claims 85, 90, 107-112, and 118. However, it would have been obvious to one of ordinary skill in the art to substitute the scaling range from 0 to 10, taught by Daniel, with the scaling range from 0 to 1 with predictable results, since choosing appropriate scaling ranges for data is an arbitrary design consideration.

Daniel does not teach specifically teach combining first and second binding affinities, as in claims 85, 90, 107-112, and 118. However, it would have been obvious to combine first and second scaled binding affinities, since Daniel shows comparing the same experimental data from two different predictive methods and adjusting the data such that all data is compared on the same scaling range [p.620, Col. 2, ¶2]. The motivation would have been to obtain a consensus binding affinity from different predictive methods.

Daniel does not teach determining a second binding affinity using a second predictive method selected from quadratic, linear, anchor, profile, and structure-based methods, as in claims 85, 90, and 107-112.

Wang teaches an empirical structure-based method for assessing the binding affinity of a protein-ligand complex [Abstract]. In particular, Wang teaches binding affinity scores between 0 and 10 [Table 1]. Wang teaches a predictive scoring function that combines six different types of binding affinity scores [p.384, Col. 1]. In addition, Wang suggests that their method is especially valuable for lead optimization in drug design [p.393, Col. 1, ¶3].

It would have been obvious to someone of ordinary skill in the art at the time of the instant invention to modify the binding affinity prediction method of Daniel by replacing the matrix-based method with the empirical structure-based method taught by Wang, since Daniel shows the use of two different predictive methods [p.618, Col. 2], and since both Daniel and Wang predict binding affinity using a similar numerical scale. One of ordinary skill in the art would have been motivated to make the above modifications to improve predictive power by accounting for structural and sequence-based factors in binding affinity prediction, and by using a method predictive method that is especially valuable for lead optimization in drug design, as suggested by Wang [p.393, Col. 1, ¶3].

Response to Arguments

Applicant's arguments, filed 04/08/2008, with respect to the rejection of claims 85-92 and 109-118 under 35 U.S.C. 103(a) as being obvious over Rognan et al. in view of Welch et al. have been fully considered and are persuasive. In particular, applicant's arguments, filed 04/08/2008, that neither Rogan nor Welch teaches scaling and combining binding affinities with values between 0 and 1, have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of applicant's arguments filed 04/08/2008, that neither reference teaches scaling and combining binding affinities with values between 0 and 1.

Regarding applicant's inquiry of claims 107 and 108, it is noted that claims 107 and 108 are rejected under 35 USC 103.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached at 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Pablo S. Whaley/

Patent Examiner

Art Unit 1631

/John S. Brusca/

Primary Examiner, Art Unit 1631